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Eccentric Loading Compared with Shock Wave Treatment for Chronic Insertional Achilles Tendinopathy

A Randomized, Controlled Trial

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Background: Nonoperative management of chronic tendinopathy of the Achilles tendon insertion has been poorly studied. With the recently demonstrated effectiveness of eccentric loading and of repetitive low-energy shock wave therapy in patients with midsubstance Achilles tendinopathy, the aim of the present randomized, controlled trial was to verify the effectiveness of both procedures exclusively in patients with insertional Achilles tendinopathy.

Methods: Fifty patients with chronic (six months or more) recalcitrant insertional Achilles tendinopathy were enrolled in a randomized, controlled study. All patients had received treatment, including local injections of an anesthetic and/or corticosteroids, a prescription of nonsteroidal anti-inflammatory drugs, and physiotherapy, without success for at least three months. A computerized random-number generator was used to draw up an allocation schedule. Twenty-five patients were allocated to receive eccentric loading (Group 1), and twenty-five patients were allocated to treatment with repetitive low-energy shock wave therapy (Group 2). Analysis was on an intention-to-treat basis. Primary follow-up was at four months, and afterward patients were allowed to cross over. The last follow-up evaluation was at one year after completion of the initial treatment. The patients were assessed for pain, function, and activity with use of a validated questionnaire (the Victorian Institute of Sport Assessment-Achilles [VISA-A] questionnaire).

Results: At four months from baseline, the mean VISA-A score had increased in both groups, from 53 to 63 points in Group 1 and from 53 to 80 points in Group 2. The mean pain rating decreased from 7 to 5 points in Group 1 and from 7 to 3 points in Group 2. Seven patients (28%) in Group 1 and sixteen patients (64%) in Group 2 reported that they were completely recovered or much improved. For all outcome measures, the group that received shock wave therapy showed significantly more favorable results than the group treated with eccentric loading ($p = 0.002$ through $p = 0.04$). At four months, eighteen of the twenty-five patients from Group 1 had opted to cross over, as did eight of the twenty-five patients from Group 2. The favorable results after shock wave therapy at four months were stable at the one-year follow-up evaluation.

Conclusions: Eccentric loading as applied in the present study showed inferior results to low-energy shock wave therapy as applied in patients with chronic recalcitrant tendinopathy of the insertion of the Achilles tendon at four months of follow-up. Further research is warranted to better define the indications for this treatment modality.

Level of Evidence: Therapeutic Level I. See Instructions to Authors for a complete description of levels of evidence.

Achilles tendon injuries occur frequently in runners and in athletes who play sports that involve jumping, and they are also common in the general population. The precise etiology and natural history of these injuries remains unknown^{1,2}.

Khan et al.³ and Maffulli et al.⁴⁻⁶ popularized the term Achilles tendinopathy to describe the triad of tendon pain, swelling, and impaired performance. From a functional perspective, it is helpful to classify Achilles tendinopathy as insertional⁶—symptoms that occur at the bone-tendon

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junction—or as noninsertional⁵—those that occur more proximally.

Although Achilles tendinopathy has been studied extensively, there is a clear lack of properly conducted scientific research to clarify its optimal management^{4,6-8}. In a recent Cochrane review⁹, only nine clinical trials, consisting of 697 patients, were of sufficient quality to be considered. Overall, there was insufficient evidence from the randomized, controlled trials to determine which method is the most appropriate to manage Achilles tendinopathy, and not a single trial concentrated exclusively on the treatment of insertional Achilles tendinopathy.

Several studies have demonstrated that eccentric training can be an effective treatment for insertional and noninsertional tendinopathies¹⁰⁻¹⁴, although Woodley et al.¹⁵ recently stressed the dearth of high-quality research in support of the clinical effectiveness of eccentric exercises over other treatments. In an uncontrolled observational study, a twelve-week eccentric calf-muscle strength-training program led to a satisfactory outcome in 89% of 101 patients with chronic painful Achilles tendinosis at the midportion¹³.

Information regarding the application of shock wave treatment for Achilles tendinopathy is sparse^{16,17}. Costa et al.¹⁸ found no difference in pain relief between repetitive low-energy shock wave treatment and a placebo group¹⁹. Rompe et al.²⁰, in a triple-arm randomized, controlled trial comparing eccentric loading, repetitive low-energy shock wave therapy, and a wait-and-see policy in the treatment of midsubstance Achilles tendinopathy, found that eccentric loading and shock wave treatment yielded comparable success rates (60% and 52%, respectively), which were substantially better than the wait-and-see policy (24%). Again, we know of no single randomized clinical trial concentrating exclusively on the treatment of insertional Achilles tendinopathy.

We compared the efficacy of two protocols, eccentric calf-strengthening and repetitive low-energy shock wave therapy, for the treatment of chronic insertional Achilles tendinopathy.

Materials and Methods

We performed a randomized trial in a primary-care setting, enrolling patients from the general population who had consulted one of three participating orthopaedic physicians for Achilles tendon complaints. The patients were then referred to the clinic of one of us (J.D.R.) (Table I). In all patients, the diagnosis of tendinopathy at the insertion of the Achilles tendon (synonymous with insertional Achilles tendinopathy) was confirmed clinically. For this purpose, insertional Achilles tendinopathy was defined as localized pain over the distal part of the Achilles tendon at its insertion onto the calcaneus, with local tenderness and a reduced level of activity⁶. The Williams arc sign test²¹ and the Royal London Hospital test⁴ were applied to rule out more extensive tendinopathy or paratendinopathy involving the body of the Achilles tendon. In all patients enrolled in the study, an ultrasound study also excluded thickening of the tendon and/or an irregular tendon structure with hypochoic areas and/or an irregular fiber ori-

entation in the midportion of the tendon²². Patients presenting with superficial or retrocalcaneal fluid on the ultrasound examination as a sign of bursitis were excluded. All patients had plain radiographs of the calcaneus to identify tendon calcification. Patients showing a Haglund deformity, an osseous prominence on the posterosuperior and lateral aspect of the calcaneus with a Fowler-Philip angle of $>75^\circ$ on plain radiographs²³, were excluded.

We included patients who had an established diagnosis of chronic insertional Achilles tendinopathy for at least six months combined with failure of nonoperative management, including at least one injection of a local anesthetic and/or a corticosteroid, a prescription for an anti-inflammatory medication, and physiotherapy and/or use of orthotics or a heel lift. Patients were between the ages of eighteen and seventy years, and they had to be able to complete questionnaires and to give informed consent.

We excluded from the study those patients who had received peritendinous injections (local anesthetic and/or corticosteroids) within the previous four weeks, patients in whom symptoms had been present for less than six months, and patients with other conditions that could contribute substantially to posterior ankle pain, such as classic midsubstance Achilles tendinopathy, ankle arthritis, radiculopathy, or systemic neurological conditions. Patients were also excluded if they had congenital or acquired deformities of the knee and ankle, prior surgery of the ankle or the Achilles tendon, a prior Achilles tendon rupture, or a dislocation or fracture in the area in the preceding twelve months.

Study Protocol

A nurse who was not directly involved in the management of the patients checked all selection criteria and enrolled fifty patients. Informed consent was obtained. The local medical ethics committee had approved the protocol.

A computerized random-number generator was used to formulate an allocation schedule. Subjects were randomized to either treatment, with use of the method of randomly permuted blocks. The randomization scheme was generated with use of the web site www.randomization.com. Fifty patients were randomized into five blocks. The assignment of patients to eccentric loading or to shock wave therapy took place after final selection and baseline assessment by the senior author (J.D.R.). A medical assistant allocated interventions by means of opaque sealed envelopes that were marked according to the allocation schedule (Fig. 1). The medical assistant was unaware of the size of the blocks.

Patients were asked to avoid pain-provoking activities throughout the twelve-week treatment period. Walking and bicycling were allowed if they could be performed with only mild discomfort. Light jogging on flat ground and at a slow pace was allowed after four to six weeks, but only if it could be undertaken without pain. Thereafter, activities could be gradually increased if severe tendon pain did not occur.

The option to cross over to the other treatment group or to choose any other therapy was provided to patients who

TABLE I Baseline Characteristics of Patients

Characteristic	Group 1 (Eccentric Loading) (N = 25)	Group 2 (Shock Wave Therapy) (N = 25)
Age* (y)	39.2 (10.7)	40.4 (11.3)
Female patients†	14 (56)	16 (64)
Duration of symptoms* (mo)	24.8 (8.2)	26.3 (10.7)
Nonathletic patients†	11 (44)	10 (40)
Athletic patients†	14 (56)	15 (60)
Affected feet (no. [%] of feet)	30 (100)	31 (100)
Left feet	13 (43)	15 (48)
Right feet	17 (57)	16 (52)
Previous treatment†		
Nonsteroidal anti-inflammatory drugs	25 (100)	25 (100)
Physical therapy	25 (100)	25 (100)
Orthotics	25 (100)	25 (100)
Conventional stretching exercises	25 (100)	25 (100)
Injections	25 (100)	25 (100)
≥2 cortisone injections	14 (56)	12 (48)
Shock wave therapy	0 (0)	0 (0)
Surgery	0 (0)	0 (0)
VISA-A score*‡	52.7 (8.4)	53.2 (5.8)
General assessment rated on 6-point Likert scale*	5.4 (0.6)	4.9 (0.9)
Load-induced pain assessed on a numeric rating scale from 0 to 10*	6.8 (1.0)	7.0 (0.8)
Pain threshold* (kg)	1.4 (0.7)	1.6 (0.8)
Tenderness at 3 kg assessed on a numeric rating scale from 0 to 10*	6.2 (3.7)	6.5 (3.4)

*The values are given as the mean, with the standard deviation in parentheses. †The values are given as the number of patients, with the percentage in parentheses. ‡The VISA-A (Victorian Institute of Sport Assessment-Achilles questionnaire) ranged from 1 to 100.

did not feel that they had completely recovered or had much improvement at four months after the start of the trial.

Methods of Treatment

Eccentric Training

Patients were instructed on how to perform the eccentric training^{13,14,24,25}. The senior author demonstrated how to perform the eccentric exercises to each patient on an individual basis. Patients were given practice instruction and a written manual on how to progress. Proper form and technique were assessed by a medical assistant after six weeks. In the beginning, the loading consisted of the body weight. The patient stood on a step with all of his or her body weight on the injured leg. From an upright body position and standing with all body weight on the forefoot, with the ankle joint in plantar flexion, the calf-muscle was loaded by having the patient lower the affected limb by dorsiflexing the ankle until the heel was well below the level of the step with the ankle in maximum dorsiflexion. The exercises were performed with the knee straight to load the gastrocnemius eccentrically and with the knee flexed to load the soleus eccentrically. Patients only loaded the calf-muscle eccentrically; no concentric loading was performed, as

the patients were instructed to use the uninjured leg and/or their arms to get back to the start position. Patients aimed to complete three sets of fifteen repetitions with one minute of rest between the sets twice a day, seven days per week, for twelve weeks. Patients started with one set of ten repetitions on the first day of exercises and gradually progressed to three sets of fifteen repetitions by the seventh day, aiming to complete three sets of fifteen repetitions twice a day by the second week of treatment. Patients were advised to continue the exercises through mild or moderate pain, stopping only if the pain became unbearable. When these exercises could be completed with no pain or discomfort, the patients progressed to carry a backpack containing 5 kg of books. They were invited to continue to add weight in multiples of 5 kg if they did not have pain in the Achilles tendon by the end of the third set of the eccentric exercises. The patients were asked to refrain from other forms of physical therapy and not to use insoles²⁴. If necessary, paracetamol (2000 to 4000 mg daily) or naproxen (1000 mg daily) was prescribed. Patients were instructed to do the exercises on a daily basis, and they were asked if they had done so at the follow-up visits. However, rigid control of compliance was not possible.

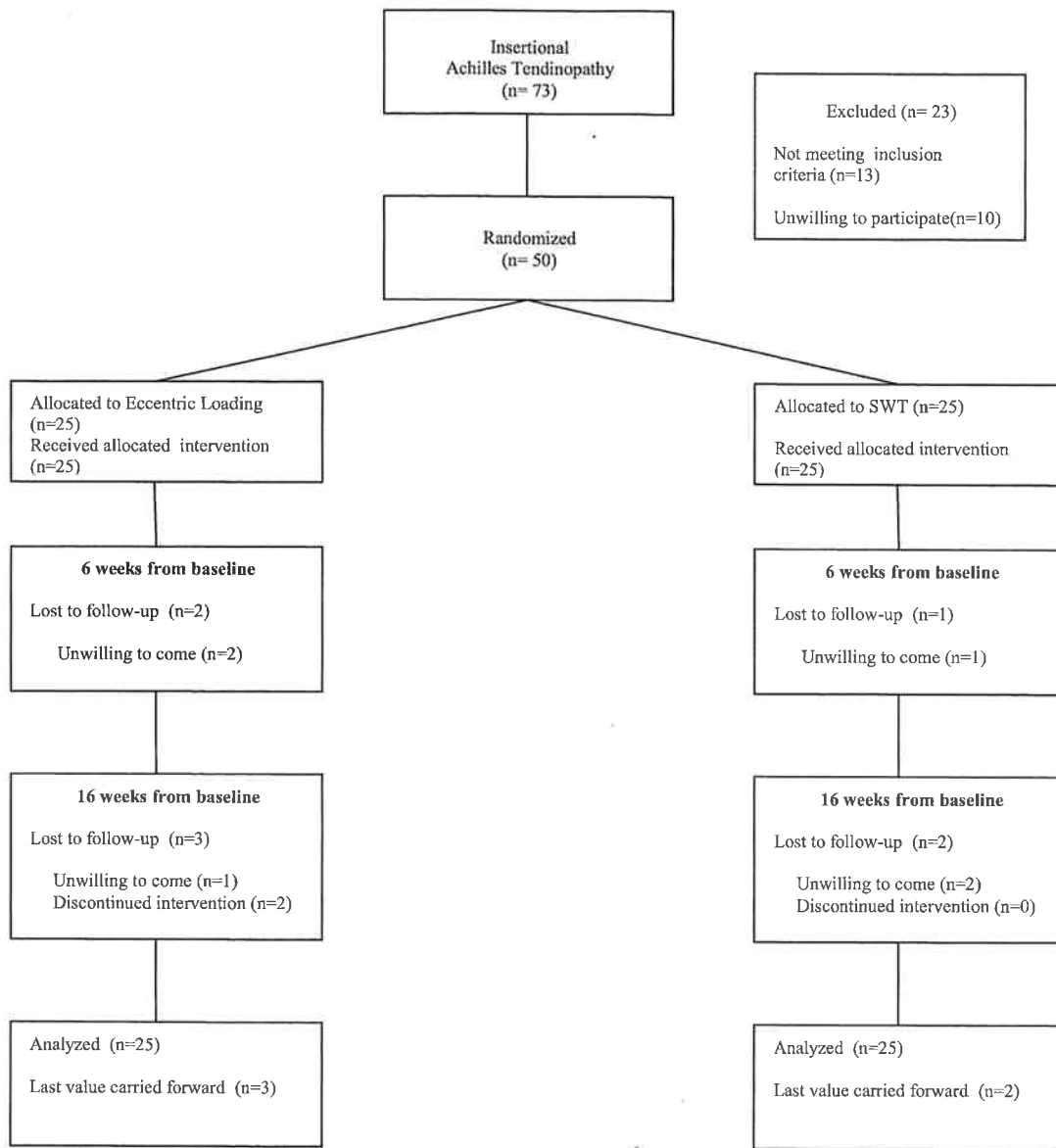


Fig. 1

Flow chart of the trial until the primary follow-up at four months from baseline. SWT = shock wave treatment.

Shock Wave Therapy

Shock wave therapy was administered to the patients by the senior author. A radial shock wave device (EMS Swiss Dolor-Clast, Munich, Germany) was used. A projectile in a handpiece is accelerated by a pressurized air source and strikes a 15-mm-diameter metal applicator. The energy generated is transmitted to the skin as a shock wave through a standard, commercially available ultrasound gel. The wave then disperses radially from the application site into the tissue to be treated. The energy generated depends considerably on the working pressure to which the device has been set. Following our previous recommendation²⁰, shock wave therapy was performed three times spaced one week apart. At each of the three sessions, 2000 pulses were applied with a pressure of 2.5 bars (equal to an energy flux density of 0.12 mJ/mm²). The treatment fre-

quency was eight pulses per second. With use of the principle of clinical focusing, the area of maximal tenderness was treated in a circumferential pattern, starting at the point of maximum pain. No local anesthetic was applied.

Details of each treatment session and of any adverse effects were reported on standardized forms and given to the medical assistant. All concomitant interventions during the four-month follow-up period were discouraged. If necessary, paracetamol (2000 to 4000 mg daily) or naproxen (1000 mg daily) was prescribed. Patients were encouraged to await further spontaneous improvement.

Outcome Assessment

Following the investigations on eccentric loading by Alfredson¹² and Fahlstrom et al.¹³, the main follow-up point was chosen